REMARKS

Applicants respectfully request reconsideration of this application as amended.

Office Action Rejections Summary

Claims 1, 2, 5 – 9, 11 – 13, 15 – 19, 21 – 24, 26, 28 – 30, 32, 34, 36, and 40 – 47 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,752,518 to McGee et al. (hereinafter "McGee"). Claims 3, 4, 10, 14, 20, 25, 27, 31, 33, 35, and 39 have been rejected under 35 U.S.C. §103(a) as being unpatentable over McGee and further in view of U.S. Patent 4,587,972 to Morantte, Jr. (hereinafter "Morantte").

Status of Claims

Claims 1 – 5, 7 – 21, 26, 27, 32 – 35, and 44 – 46 remain pending in the application. Claims 1, 15, 26, 32, 34, and 44 have been amended to define the invention more properly. The amended claims are supported by the specification and no new matter has been added. Claims 6, 22 – 25, 28 – 31, 36 – 43, and 47 have been canceled without prejudice. No new claims have been added.

Claim Rejections Under 35 U.S.C. §102(b)

Claims 1, 2, 5 – 9, 11 – 13, 15 – 19, 21 – 24, 26, 28 – 30, 32, 34, 36, and 40 – 47 have been rejected under 35 U.S.C. 102(b) as being anticipated by McGee. Applicants respectfully submit that claims 1, 2, 5 – 9, 11 – 13, 15 – 19, 21 – 24, 26, 28 – 30, 32, 34, 36, and 40 – 47 are not anticipated by McGee.

Amended independent claim 1 recites:

> An apparatus comprising:
> an intravascular device to perform a therapeutic treatment; and
> at least one optical fiber disposed within a sheath and disposed within the intravascular device, ***the at least one optical fiber also disposed within an enclosure that is bonded to at least one point***

along the sheath, the optical fiber configured to provide diagnostic information before and after the therapeutic treatment.

(emphasis added)

Amended independent claim 26 recites:

An apparatus comprising:
a catheter comprising a catheter shaft having a lumen therein;
a sheath slidably disposed over the catheter shaft; the catheter shaft and the sheath defining an intraluminal gap extending longitudinally therebetween; and
at least one optical fiber disposed within the intraluminal gap, ***the at least one optical fiber also disposed within an enclosure that is bonded to at least one point along the sheath***, the apparatus capable of both diagnostic and therapeutic purposes.

(emphasis added)

Amended independent claim 32 recites:

A system for sensing vessel and blood characteristics, the system comprising:
a data processing system; and
an apparatus coupled to the data processing system, the apparatus comprising an intravascular device to perform a therapeutic treatment and at least one optical fiber disposed within a sheath and disposed within the intravascular device, ***the at least one optical fiber also disposed within an enclosure that is bonded to at least one point along the sheath***, the optical fiber configured to provide diagnostic information before and after the therapeutic treatment.

(emphasis added)

Amended independent claim 34 recites:

A method of sensing vessel and blood characteristics, the method comprising:
inserting an apparatus into a vasculature of a patient, the apparatus comprising an intravascular device to perform a therapeutic treatment and at least one optical fiber disposed within a sheath and disposed within the intravascular device, ***the at least one optical fiber also disposed within an enclosure that is bonded to at least one point along the sheath***, the optical fiber to transmit a light radiation signal therethrough;
advancing the apparatus to a location in the vasculature;

operating a data processing system coupled to the apparatus to transmit a plurality of light radiation signals to the location in the vasculature and a plurality of reflected light radiation signals to a detector in the data processing system; and

processing the plurality of reflected light radiation signals to determine vessel and blood characteristics.

McGee discloses a fiber optic assembly for visualization of tissue. The IAE 50 comprises the distal end 220 of an optic fiber path 222. The distal end 220 is embedded within an inner sheath 224, which is carried within an outer sheath 226. The outer sheath 226 extends in the distal body region 40, within the support structure 20. The inner sheath 224 includes a lens 228, to which the distal fiber path end 220 is optically coupled. The inner sheath 224 terminates in an angled mirror surface 230, which extends beyond the end of the outer sheath 226. The surface 230 reflects optical energy along a path that is generally perpendicular to the axis of the distal end 220. (McGee, col. 8, lines 18 – 28, and FIG. 25). Nothing in McGee discloses a separate enclosure that covers inner sheath 224 (which forms optical fiber path 222). Moreover, nothing in McGee discloses the bonding of the inner sheath with the outer sheath. With respect to this absent feature, the Office Action states, "Figures 1 and 5A of McGee shows that the optical fiber 34 is coupled to the tubular inner member and is movable within the lumen." (Office Action, dated 07/14/04, page 3). Applicant respectfully submits that McGee does not disclose any bonding of an enclosure for the fiber optic path with the sheath. In fact, there is no separate enclosure for the fiber optic path other than inner sheath 224. In contrast, independent claims 1, 26, 32, and 34 each include the limitation of "the at least one optical fiber also disposed within an enclosure that is bonded to at least one point along the sheath." As such, applicant respectfully submits that claims 1, 26, 32, and 34 are not anticipated by McGee under 35 U.S.C. §102(b) and request removal of the rejection.

Claims 2 – 5, 7 – 14 depend either directly or indirectly from independent claim 1. Claim 27 depends from independent claim 26. Claim 33 depends from independent claim

32. Claim 35 depends from independent claim 34. As such, all these dependent claims include the limitation of "the at least one optical fiber also disposed within an enclosure that is bonded to at least one point along the sheath." Accordingly, claims 2 – 5, 7 – 14, 27, 33, and 35 are also not anticipated by McGee under 35 U.S.C. §102(b).

Amended independent claim 15 recites:

> A catheter comprising:
> a catheter shaft having an elongated outer member disposed about an tubular inner member and an intraluminal gap extending longitudinally between the outer member and the inner member; and
> at least one optical fiber disposed within a sheath and disposed within the intraluminal gap, ***the at least one optical fiber also disposed within an enclosure that is bonded to at least one point along the inner member***, the catheter capable of both diagnostic and therapeutic purposes. (emphasis added)

McGee discloses a fiber optic assembly for visualization of tissue. The IAE 50 comprises the distal end 220 of an optic fiber path 222. The distal end 220 is embedded within an inner sheath 224, which is carried within an outer sheath 226. The outer sheath 226 extends in the distal body region 40, within the support structure 20. The inner sheath 224 includes a lens 228, to which the distal fiber path end 220 is optically coupled. The inner sheath 224 terminates in an angled mirror surface 230, which extends beyond the end of the outer sheath 226. The surface 230 reflects optical energy along a path that is generally perpendicular to the axis of the distal end 220. (McGee, col. 8, lines 18 – 28, and FIG. 25). Nothing in McGee discloses a separate enclosure that covers inner sheath 224 (which forms optical fiber path 222). Moreover, nothing in McGee discloses the bonding of the inner sheath with the outer sheath. With respect to this absent feature, the Office Action states, "Figures 1 and 5A of McGee shows that the optical fiber 34 is coupled to the tubular inner member and is movable within the lumen." (Office Action, dated 07/14/04, page 3).

Applicants respectfully submit that McGee does not disclose any bonding of an enclosure for the fiber optic path with the sheath. In fact, there is no separate enclosure for the fiber optic path other than inner sheath 224. In contrast, independent claim 15 includes the limitation of "the at least one optical fiber also disposed within an enclosure that is bonded to at least one point along the inner member." As such, applicant respectfully submits that claim 15 is not anticipated by McGee under 35 U.S.C. §102(b) and request removal of the rejection.

Claims 16 – 21 depend either directly or indirectly from independent claim 15. As such, these dependent claims include the limitation of "the at least one optical fiber also disposed within an enclosure that is bonded to at least one point along the inner member." Accordingly, claims 16 – 21 are also not anticipated by McGee under 35 U.S.C. §102(b).

Amended independent claim 44 recites:

> A catheter, comprising:
> a catheter inner shaft member having a first lumen adapted to receive an optical fiber sensor, ***the optical fiber disposed within an enclosure that is bonded to at least one point along an interior surface of a wall that forms the first lumen***, a second lumen adapted to receive a guidewire, and a third lumen adapted to received a therapeutic drug, wherein the optical fiber is configured to provide diagnostic information before and after a therapeutic treatment.
>
> (emphasis added)

McGee discloses a fiber optic assembly for visualization of tissue. The IAE 50 comprises the distal end 220 of an optic fiber path 222. The distal end 220 is embedded within an inner sheath 224, which is carried within an outer sheath 226. The outer sheath 226 extends in the distal body region 40, within the support structure 20. The inner sheath 224 includes a lens 228, to which the distal fiber path end 220 is optically coupled. The inner sheath 224 terminates in an angled mirror surface 230, which extends beyond the end

of the outer sheath 226. The surface 230 reflects optical energy along a path that is generally perpendicular to the axis of the distal end 220. (McGee, col. 8, lines 18 – 28, and FIG. 25). Nothing in McGee discloses a separate enclosure that covers inner sheath 224 (which forms optical fiber path 222). Moreover, nothing in McGee discloses the bonding of the inner sheath with the outer sheath. With respect to this absent feature, the Office Action states, "Figures 1 and 5A of McGee shows that the optical fiber 34 is coupled to the tubular inner member and is movable within the lumen." (Office Action, dated 07/14/04, page 3). Applicant respectfully submits that McGee does not disclose any bonding of an enclosure for the fiber optic path with the sheath. In fact, there is no separate enclosure for the fiber optic path other than inner sheath 224. In contrast, independent claim 44 includes the limitation of "the optical fiber disposed within an enclosure that is bonded to at least one point along an interior surface of a wall that forms the first lumen." As such, applicant respectfully submits that claim 44 is not anticipated by McGee under 35 U.S.C. §102(b) and request removal of the rejection.

Claims 45 – 46 depend either directly or indirectly from independent claim 44. As such, these dependent claims include the limitation of "the optical fiber disposed within an enclosure that is bonded to at least one point along an interior surface of a wall that forms the first lumen." Accordingly, claims 45 – 46 are also not anticipated by McGee under 35 U.S.C. §102(b).

Claim Rejections Under 35 U.S.C. §103(a)

Claims 3, 4, 10, 14, 20, 25, 27, 31, 33, 35 and 39 have been rejected under 35 U.S.C. §103(a) as being unpatentable over McGee and further in view of Morantte. Applicant respectfully submits that claims 3, 4, 10, 14, 20, 25, 27, 31, 33, 35 and 39 are patentable over McGee and Morantte. Claims 3, 4, and 14 depend from independent claim 1, claim 27 depends from independent claim 26, claim 33 depends from independent claim 32, and claim 35 depends from independent claim 34. As such, claims 3, 4, 14, 27, 33, and 35 each include the limitation of "the at least one optical fiber also disposed within an enclosure that is bonded to at least one point along the sheath." Claim 20 depends from independent claim 15 and thus includes the limitation of "the at least one optical fiber also disposed within an enclosure that is bonded to at least one point along the inner member." As discussed above, nothing in McGee discloses or suggests these limitations.

Morantte discloses an intravascular device in which the chamber 30 of the housing 12 contains a fiberoptic bundle 60 comprising a plurality of elongated, fiberoptic fibers 62 disposed in substantially axially parallel relation and extending longitudinally within the chamber from the proximal end portion 15 to the distal end portion 18. The fibers 62 can be constructed of any suitable conductive material adapted to conduct light from a light source axially through the fiber and, preferably, the fibers are constructed of such material which is particularly adapted to conduct light from a laser-generating source axially therethrough and to emit such light from the tip 19. (Morantte, col. 4, lines 43 – 55, and FIGS. 2 – 4). Morantte also discloses a sheath that covers not the fiberoptic bundle 60, but rather an electrode bundle 85 having a plurality of electrical conductors or electrodes 87 extending longitudinally within the chamber 30. (Morantte, col. 6, lines 38 – 44, and FIGS. 2 – 4). Moreover, nothing in Morantte discloses or suggests an enclosure for the fiberoptic bundle

that is bonded to a sheath or inner member. As such, Morantte fails to cure the deficiency of McGee.

It is respectfully submitted that Morantte and McGee do not teach or suggest a combination with each other. The office Action states:

> McGee does not specifically disclose a measurement of vessel and blood characteristics such as hemodynamic characteristics. In Morantte, an intravascular catheter is used to diagnose and treat blood vessel by measuring hemodynamic characteristics of the blood vessel using optical source or laser energy to assess the level of treatment or therapy required. Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Morantte to improve McGee's apparatus where it includes the therapy assessment by imaging.
> (Office Action, 07/14/04, page 4)

Here, the Office Action merely states an advantage of substituting the catheter of Morantte with the catheter of McGee, without explaining what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination.

Even if Morantte and McGee were combined, it would still not result in the limitations of independent claims 1, 15, 26, 32, and 34. As stated above, claims 1, 26, 32, and 34 each include the limitation of "the at least one optical fiber also disposed within an enclosure that is bonded to at least one point along the sheath" and claim 15 includes the limitation of "the at least one optical fiber also disposed within an enclosure that is bonded to at least one point along the inner member." The combination of Morantte and McGee does not teach these limitations. As such, the combination cannot be interpreted to disclose the limitations of claims 3, 4, 14, 20, 27, 33, and 35. Therefore, applicant respectfully requests the withdrawal of the rejection of the claims under 35 U.S.C. § 103(a) over the combination.

If the allowance of these claims could be facilitated by a telephone conference, the Examiner is invited to contact Suk Lee at (408) 720-8300. If there are any additional charges, please charge our Deposit Account No. 02–2666.

Respectfully submitted,

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